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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/690,828	10/23/2003	Ewen James Crawford Kellar	553-81	5416
23117	7590	10/05/2005	EXAMINER	
NIXON & VANDERHYE, PC 901 NORTH GLEBE ROAD, 11TH FLOOR ARLINGTON, VA 22203			IMAM, ALI M	
			ART UNIT	PAPER NUMBER
			3737	

DATE MAILED: 10/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

6

Office Action Summary	Application No.		Applicant(s)	
	10/690,828		CRAWFORD KELLAR ET AL.	
	Examiner		Art Unit	
	Ali Imam		3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 09/984,147.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>10/23/3</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Inventorship

1. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Priority

2. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Drawings

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: "32" found in page 7, line 6 of the specification. It is suggested to replace "32" with -- 32a, 32b -- in the specification.

4. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference sign(s) not mentioned in the description: "52", "54", "56", and "72". A proposed drawing correction, corrected drawings, or amendment to the specification to add the reference sign(s) in the description, are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

5. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the “foundation layer” claimed in claims 3, 4, 26, and 27 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

6. The abstract of the disclosure is objected to because the form and legal phraseology often used in patent claims, such as “means” should be avoided (see line 1 of the abstract). Correction is required. See MPEP § 608.01(b).

7. The disclosure is objected to because of the following informalities: it appears that in page 5, line 5 of the specification, “Figure 9” should be changed to -- Figures 9A-9D --; in line 7 of the page “Figure 10” should be changed to -- Figures 10A-10D --; in line 9 of the page “Figure 11” should be changed to -- Figures 11A-11D --; and in line 15 of the page, “Figure 14” should be changed to -- Figures 14A-14D --. Appropriate correction is required.

8. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Claim Objections

9. Claims 2, 3, 5, and 6 are objected to because of the following informalities: in line 1 of claims 2, 3, 5, and 6, “and” should be deleted; in claim 2, line 2, “element” should be changed to

-- elements --; and in claim 3, line 2, "element" should be changed to -- two elements --.

Appropriate correction is required.

10. Claim 19 is objected to because of the following informalities: it appears that in line 2 of the claim, "carry" should be changed to -- carrier --. Appropriate correction is required.

11. Claim 23 is objected to because of the following informalities: in line 1 of the claim, it appears that the applicant left out other necessary figures (see the phrase "with reference to Figures 1 to - of the accompanying drawings"). Appropriate correction is required.

12. Claim 26 is objected to because of the following informalities: it appears that claim 26 should depend on claim 24 instead of claim 1 because claim 1 is not a method claim. The examiner assumes that it is a typographical error. Accordingly, for examining purposes the examiner has assumed that claim 26 is dependent on claim 24. Appropriate correction is required.

13. Claim 43 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 42. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). For examination purposes, the examiner has assumed that claim 43 should have the limitation -- the step of applying the layers along a substantial length of said elongate member --.

Claim Rejections - 35 USC § 112

14. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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15. Claims 1-23, 30, 36, and 41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

16. Claim 1 recites the limitation "said gas" in line 9. There is insufficient antecedent basis for this limitation in the claim.

17. Claim 3 recites the limitation "said element" in line 2. There is insufficient antecedent basis for this limitation in the claim. It is suggested to change "said element" to -- said two elements --.

18. Claims 8, 14, 30, and 36 contain the trademark/trade name HedrothaneTM and claims 18 and 39 contain the trademark/trade name ChronoflexTM. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name HedrothaneTM is used to identify/describe hydrophilic material and ChronoflexTM is used to identify/describe a chromate free water based primer and, accordingly, the identification/description is indefinite.

19. Claim 20 recites the limitation "the first to the second reactive agents" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

20. Claim 23 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite in that it fails to point out what is included or excluded by the claim language. This claim is an omnibus type claim.

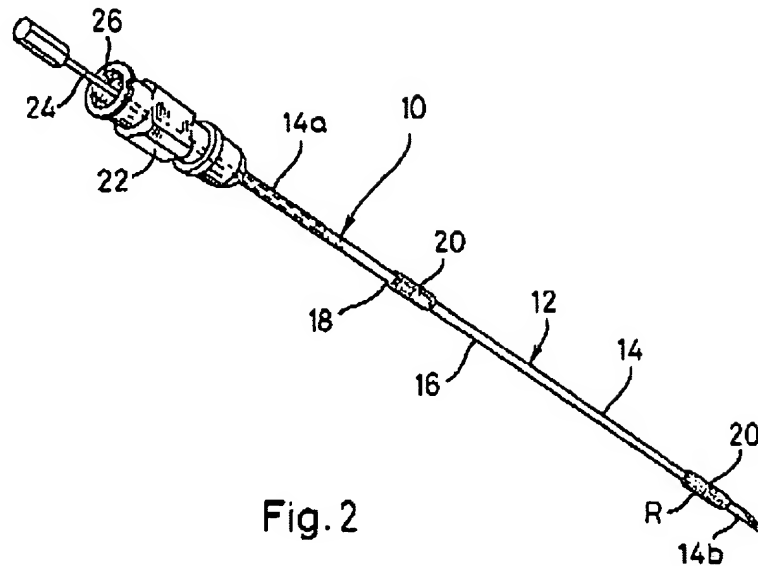
21. Claim 41 recites the limitation "the first and second reactive elements" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

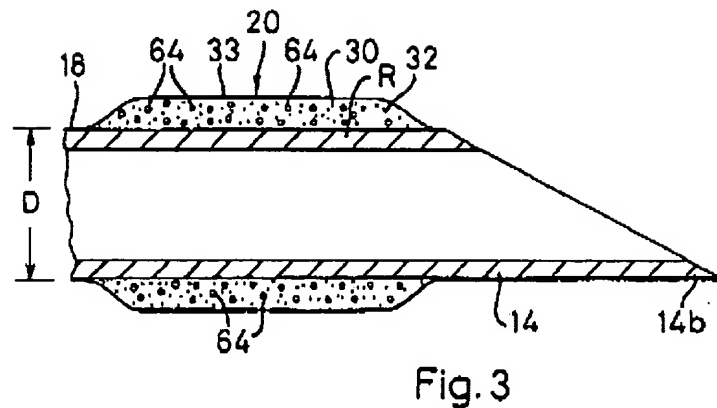
22. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

23. Claims 1, 3-7, 9-10, 17-22, 24, 26-29, 31-32, and 38-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Joseph (WO 98/18387 of record) in view of Violante et al. (US 6,106,473). Joseph discloses in page 9, line lines 1-28 and shows in Fig. 2 (reproduced below), an instrument (10) insertable into a medium and being capable of detection by sonic imaging equipment comprising an elongate member (14) for insertion into the medium and



having a region the position of which it is desirable to monitor, bubble generating means (effervescent material 32 of Fig. 3) for generating a plurality of discrete mobile gas bubbles at the region, whereby the bubbles are detectable by sonic imaging equipment wherein the bubble generating means comprises two elements, sodium hydrogen carbonate and citric powder, (col. 4, line7) which, upon contact with each other in the presence of fluid react with each other to produce the gas bubbles within a fluid (col. 3, lines 1-5). Joseph further teaches in Fig. 3 (reproduced below) a fluid permeable carrier material (30). Joseph teaches a single radially displaced layer (coating 20) containing both elements of the bubble generating means.



Joseph differs from the claimed invention because it does not explicitly disclose that the two elements of the bubble generating means comprise first and second radially displaced layers of the elements within the carrier material.

Violante et al. (hereinafter "Violante") discloses a coating layer (applicant's bubble generating means) containing two elements, a bicarbonate salt (obviously includes sodium hydrogen carbonate; see col. 10, line 60) and an acid (obviously includes citric acid; see col. 3, lines 38-50). Violante teaches that in an alternative form the bubble generating means containing the two elements could be applied to a medical instrument, such as a needle (col. 6, line 15), as more than one layers (col. 11, line 42) for optimum gas production in order to improve the visibility of the instrument when viewed using ultrasound imaging techniques (col. 1, lines 11-14).

Violante is evidence that ordinary skill in the art of ultrasound imaging would find a reason, suggestion or motivation to form the bubble generating means containing the two elements as first and second radially displaced layers within the fluid permeable carrier material.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the bubble generating means of Joseph by forming the two

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elements in first and second radially displaced layers of the elements in order to increase gas production so that the visibility of the instrument is improved when viewed using ultrasound imaging techniques, as per the teachings of Violante.

Accordingly, claims 1 and 24 would have obvious.

As to claims 3, 4, 26, and 27, Joseph's coating (20) is considered the foundation layer situated on the instrument upon which the elements containing layers are deposited (see page 9, lines 10-13). Joseph further teaches that the foundation layer comprises a fluid permeable layer (page 9, line 25).

As to claims 7 and 29, Joseph teaches that the carrier material comprises a hydrophilic material (page 4, line 22).

As to claims 9, 10, 31, and 32, Joseph teaches in page 5, line 6 that the two elements comprise citric acid and sodium hydrogen carbonate. It is common and known in the art to use dissolved citric acid and sodium hydrogen carbonate for optimum results. Accordingly, claims 10 and 32 would have at least been obvious.

As to claims 5, 6, 17, 18, 28, 38, and 39, Joseph differs from the claimed invention because it does not disclose expressly the step and structure for pre coating the instrument surface by a primer layer.

Violante discloses in col. 11, lines 53-57, the step and structure for pre coating the instrument by a primer layer typically including a polyurethane based primer (col. 12, line 28 and col. 16, lines 45-50) or other suitable primers (such as an acid etched layer or water based primer) known to one skilled in the art (col. 12, lines 23-24). According to the applicant's Cytec BR6757 is a preferable water based primer. Therefore, one of ordinary skill in the art would

know that Joseph's broad limitation of a polyurethane based primer includes Chronoflex™. Violante further discloses that the instrument is treated with a primer layer in order to enable strong adhesion of the echogenic coating (applicant's bubble generating means) to the instrument.

Violante is evidence that ordinary workers in the art of ultrasound imaging would find a reason, suggestion or motivation to pre coat the medical instrument by a primer layer.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to pre coat the medical instrument of Joseph by a primer before applying the bubble generating means containing the first and second layers in order to provide strong adhesion of the bubble generating means to the instrument wherein the bubble generating means comprising the first and second layers of the two elements.

Accordingly, claims 5, 6, 17, 18, 28, 38, and 39 would have been obvious.

As to claims 19 and 40, Joseph teaches the step and structure for adding the first and second elements to a carrier material to form the layers in which the elements are added to the carrier material in a ratio of 3:7 (page 5, line 10), which is approximately 42% ($3/7 \times 100$) by weight. This ratio is obviously within the range between 20% and 200% by weight.

As to claims 20 and 41, Joseph teaches in page 5, line 9 that the first and second elements are added in equal amount and therefore, in a ratio substantially 50/50 by weight.

As to claims 21, 22, 42, and 43, Joseph teaches in the abstract that the layers may be applied at one or more discrete portions, or in the alternative, along a substantial length of the elongate member (see also page 3, line 30).

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24. Claims 2, 11-13, 25, and 33-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Joseph (WO 98/18387) in view of Violante et al. (US 6,106,473) as applied to claims disclosure in page 3, lines 4-5, Chronoflex™ is a preferable polyurethane based primer and 1, 3-7, 9-10, 17-22, 24, 26-29, 31-32, and 38-43 above and further in view of Carlin et al. (US 5,912,012).

The combined invention of Joseph and Violante teaches all the limitations of the claimed subject matter except for mentioning specifically that one of the two layers contains sodium hydrogen carbonate and the other layer contains citric acid wherein the layers are separated by an intermediate layer.

Carlin et al. (hereinafter "Carlin") teaches in Fig. 1 (reproduced below), an effervescent system containing three layers wherein the first, outer, layer (12) contains either the acidic element (e.g., the citric acid) or the basic element (e.g., the sodium hydrogen carbonate), the second, inner, layer (14) contains the other element that is not selected for the first layer (12), and the third, intermediate, layer (16) that is not chemically involved with the acidic or the basic

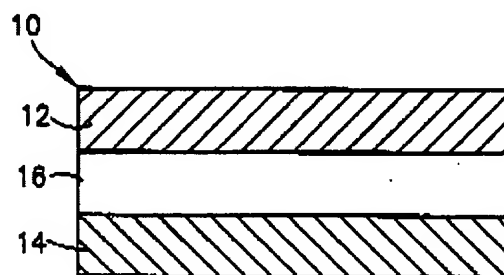


FIG. 1

element (col. 3, lines 50-54). Carlin further discloses that the intermediate layer is used for separating the first and second layers containing the two elements for improving the handling of

the two elements (col. 3, line 6) and thereby minimizing reaction between layers prior to immersion in a liquid (col. 4, lines 30-32). The applicant may argue that the effervescent system of Carlin is from a different field of endeavor (dental cleanser). However, both Joseph's effervescent materials and Carlin's effervescent materials perform the same function that is to produce gas bubbles. Violante teaches in col. 8, lines 51-57, that gas bubbles are acoustically reflective in ultrasound applications and increases the visibility of a structure containing a coating that is capable of releasing the gas bubbles in a medium.

Carlin is evidence that ordinary workers in the art of ultrasound imaging would find a reason, suggestion or motivation to add an intermediate layer to separate the first and second layers containing the two elements.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combined invention of Joseph and Violante by adding an intermediate layer in between the first and second layers containing the two elements in order to minimize the reaction between layers prior to immersion in a liquid medium, as per teachings of Carlin.

According to the teaching of Joseph in page 7, lines 5-10, it would have been obvious to one of ordinary skill in the art to make the intermediate layer such a way that it includes hydrophilic material in order to draw a small quantity of fluid from the organ tissue thereby exposing the two layers containing the effervescent materials to the action of the fluid and enhancing the effervescent effect.

25. Claims 15 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Joseph (WO 98/18387 of record) in view of Violante et al. (US 6,106,473 of record) as applied to claims

1, 3-7, 9-10, 17-22, 24, 26-29, 31-32, and 38-43 above and further in view of Urueta (US 5,885,281 of record).

The combined invention of Joseph and Violante teaches all the limitations of the claimed subject matter except for mentioning specifically that the surface is prepared by solvent degreasing or wet blasting.

Urueta teaches in col. 3, line 61 - col. 4, line 14, a solvent degreasing step in order to clean the surface of a stainless steel by removing grease and oil from the surface (col. 3, lines 62-65).

Urueta is evidence that ordinary workers in the art of ultrasound imaging would find a reason, suggestion or motivation to use the solvent decreasing step prior to applying the layers containing the two elements.

Therefore, it would have been obvious to one of ordinary skill in the art to modify the combined invention of Joseph and Violante by using the solvent degreasing step in order to remove any oil or grease from the surface of the instrument prior to applying the layers containing the two elements as per teaching of Urueta.

26. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Joseph (WO 98/18387 of record) in view of Violante et al. (US 6,106,473 of record) and Urueta (US 5,885,281 of record) as applied to claims 15 and 37 above and further in view of Ljungberg et al. (US 5,786,069 of record).

The combined invention of Joseph, Violante, and Urueta teaches all the limitations of the claimed subject matter except for mentioning specifically that the surface is prepared by wet blasting technique.

Ljungberg teaches in col. 4, lines 11-15, a technique of wet blasting for smoothing the surface of a stainless steel.

Ljungberg is evidence that ordinary workers in the art of ultrasound imaging would find a reason, suggestion or motivation to use the wet blasting step prior to applying the layers containing the two elements.

Therefore, it would have been obvious to one of ordinary skill in the art to modify the combined invention of Joseph, Violante, and Urueta by using the wet blasting step in order to smooth the surface of the instrument prior to applying the layers containing the two elements, as per teaching of Ljungberg.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ali Imam whose telephone number is 571-272-4737. The examiner can normally be reached on Mon. - Th., 8:00- 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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A handwritten signature in black ink, appearing to read 'Ali Imam', with a stylized, cursive script.

Ali Imam
Primary Examiner
Art Unit 3737

AI
10/1/5